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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,132	07/07/2006	Sarah Donald	13566.105014	7292
65989      7590      08/22/2008 KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003				
EXAMINER SIMMONS, CHRIS E				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
08/22/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

# Office Action Summary

**Application No.**

10/575,132

**Applicant(s)**

DONALD ET AL.

**Examiner**

CHRIS E. SIMMONS

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date 03/21/2008 (2 IDS's)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicants' arguments, filed 05/07/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112***

Claims 18 and 19 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of certain specific tumors with ET-743, does not enable the treatment of the vast variety of cancers within the scope of the claims as currently drafted. **This rejection is maintained and is now applicable to newly added claim 20.**

Applicant argues that the literature has described ET-743 as having “demonstrated activity” against a “broad class of solid tumor cell lines”. Applicant refers to van Kersteren (Anti-Cancer Drugs, 14(7) (2003):487-502 as support. However, the reference discloses only the *in vitro* effectiveness of ET-743 against certain tumor cells. Such a disclosure is not sufficient to show that a composition comprising ET-743 is capable of generally treating cancer, which is inclusive of treating any cancer *in vivo* and *in vitro* – and even in a human.

Applicant further argues that researchers in the art of oncology and drug development are experienced in evaluating tumor growth and that only routine experimentation is required. Particularly, Applicant alleges that Example 2 of the instant specification provides enough disclosure for a method for evaluating tumor growth. Applicant states that one of ordinary skill would have to implant a tumor in a rat, feed the rat ET-743, and then measure the tumor with calipers as described in Example 2. The claims are directed to treating cancer, which is not only inclusive of in vitro treatment but also in vivo in humans. Multiple myeloma is a cancer. The instant specification does not provide adequate disclosure to the skilled artisan on how calipers can be used to measure such a cancer and, therefore, the effectiveness of the treatment of multiple myeloma with ET-743. The Examiner maintains the position that the practice of the instant invention would require undue experimentation.

***Claim Rejections - 35 USC § 103***

Claims 9-13 and 18-19 were rejected under 35 USC 103(a) as being unpatentable over Donald et al. (Cancer Research (2003); 63(18):5902-5908; in Applicant's IDS filed 04/07/2006) in view of US 2004/0108086 A1. **This rejection is maintained and is now applicable to newly amended claims 14-17 and newly added claims 20-21.**

Applicant argues that based on statements made in the enablement rejections of the prior office action, a prima facie case of obviousness has not been made. For

instance, Applicant refers to the statement, "no one skilled in the art would accept the assertion that the instantly claimed composition could be predictably used to carry out the methods inferred by the claims and contemplated by the specification...a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success," (Office Action, page 12, lines 9-14). In addition, Applicant refers to the Office Action where it states that "It is unpredictable whether a drug can be used to treat a patient having a cancerous tumor". Applicant refers to other statements in the office action to support the allegation that a prima facie case of obviousness has not been made.

The Examiner believes that none of the office action statements Applicant is relying upon to overcome the obviousness rejection is contradictory to the motivation as to why one of ordinary skill would have found it obvious to make and use the invention. The unpredictability referred to throughout the prior office action is the unpredictability of treating the vast number of cancers) with a vast number of compounds (or with indole-3-carbinol as repeated supra). The office action, however, clearly states that the claims are enabled for the treatment of certain specific tumors with indole-3-carbinol (see page 10, 1<sup>st</sup> full paragraph), which is wholly consistent with the obviousness rejection holding that the motivation is to take advantage of the hepatoprotective properties of indole-3-carbinol against damage caused by ET-743 (which is taught to be effective in treating melanoma in the secondary reference). Accordingly, it would be obvious to treat, for example, melanoma, with the combination of drugs. This is consistent with the enablement rejection and meets the instant claims.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CHRIS E. SIMMONS** whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./  
Examiner, Art Unit 1612

***/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612***